

REMARKS

Claims 26-31 are canceled. Applicant reserves the right to pursue the original claims, or claims of equal or greater scope in related applications.

Applicant would like to advise the Office, that the claims of a related US case (11/930,941) directed to Applicant's laser system for photodamaging bacteria *in vivo*, has been deemed patentable by the US Patent and Trademark Office. Applicant proffers such information in the event it may be material to the analysis of the prior art, which follows.

Applicant respectfully requests reconsideration and further examination of the subject application in light of the foregoing amendments and the following remarks.

Summary Of Interview Per 37 CFR § 1.133

Examiner Shay met in person on September 16, 2009 with Applicant's representatives John Garvey and Matthew Fenselau. The prior art of record (Neumann et al., L'Esperence Jr., Clark et al., and Kumar et al.) was discussed. Applicant thanks Examiner Shay for his helpful comments regarding interpretation of these references.

Claim Rejections – 35 U.S.C. § 112, second paragraph

Claims 26-31 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite. The claims are purported to be unclear in terms of which step is the intended result of the irradiation. The particular claims cited are 24-31 but Applicant has construed this as a typographical error given the particular rejection. Claims 26 and 27 asserted are asserted to be indefinite for being duplicates. The Office has deemed claim 27 as depending from claim 22 for the purpose of examination.

Applicant respectfully traverses this rejection in view of the amended claims. Claims 26-31 are hereby canceled. Accordingly, Applicant requests withdrawal of this rejection.

Claim Rejections – 35 U.S.C. § 102

Claims 21, 23, 24, 26, 28, and 30 are rejected under 35 USC 102(b) as being anticipated

by Clark et al. Applicant respectfully traverses this rejection in view of the amended claims. Claims 26, 28 and 30 have been cancelled. Claims 21, 23 and 24 are clear of the Clark et al. reference.

The Clark et al. reference describes an oxygen saturation and blood pressure meter, that emits IR radiation in a range that encompasses Applicants specific frequencies. Nevertheless, the device of Clark et al. and its use, does not anticipate Applicant's claims.

Page 6 of Applicant's specification, in the first full paragraph, recites that "without the significant heat deposition normally associated in the previous art... bacteria can be selectively destroyed while minimizing unwanted hyperthermia of the irradiated tissues and the surrounding region." The Clark et al device cannot accomplish this antimicrobial effect.

Applicant claims "*delivery of said first radiation and said second radiation from said laser oscillator sub-system through said optical channel to the site of said bacterial locale thereby selectively photodamaging bacteria without significant heat deposition to tissues in said bacterial locale; wherein said first radiation and said second radiation target a bacterial intracellular chromophore at said bacterial locale and generate radical oxygen species to photodamage bacteria in said bacterial locale*" (emphasis added). While the Clark et al device delivers near IR radiation to a patient, the energy output is too low for the generation of toxic oxygen species sufficient to cause bacterial photodamage, as Applicant claims. For this reason, Clark et al cannot anticipate Applicant's invention.

Claims 21, 23, 24, 26, 28, and 30 are rejected under 35 USC 102(b) as being anticipated by Kumar et al. Applicant respectfully traverses this rejection in view of the amended claims. Claims 26, 28 and 30 have been cancelled. Claims 21, 23 and 24 are clear of the Kumar et al. reference. Kumar et al teaches a similar monitor device that can determine blood oxygenation. While the Kumar et al device delivers near IR radiation to a patient, the energy output is too low for the generation of toxic oxygen species sufficient to cause bacterial photodamage, as Applicant claims. For this reason, Kumar et al cannot anticipate Applicant's invention.

For the above reasons, Applicant requests withdrawal of these rejections.

Claim Rejections – 35 U.S.C. § 103

Kumar et al.

Claims 21-31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kumar et al. Kumar is purported as teaching applying multiple wavelengths to a patient, particularly at 930 nm which is absorbed by oxyhemoglobin. The Office asserts that Kumar et al thus teaches the method Applicant claims.

Even if Kumar et al could be properly read to disclose dosimetry ranges which overlapped or included those claimed by the Applicant, it would still not render these ranges obvious. MPEP § 2144.05 states:

Applicants can rebut a prima facie case of obviousness based on overlapping ranges by showing the criticality of the claimed range. "The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. In such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).... A prima facie case of obviousness may also be rebutted by showing that the art, in any material respect, teaches away from the claimed invention. *In re Geisler*, 116 F.3d 1465, 1471, 43 USPQ2d 1362, 1366 (Fed. Cir. 1997).

Applicant has provided clear evidence that the claimed wavelength ranges are critical to achieving microbial photodamage. In Kumar et al, the election of near IR frequencies correspond to the penetrance of such radiation, as well as its absorption (at 930 nm) by oxyhemoglobin. Nowhere in Kumar et al is any appreciation of the toxicity of such wavelength to microorganisms. Furthermore, the courts have held that "In order to show a required unexpected result, there must be a difference in kind, rather than one in degree, over the critical range." *In re Waymouth and Koury*, 499 F.2d 1273, 182 U.S.P.Q. 290, 293 (C.C.P.A. 1974). Here, the difference in kind is clear. Kumar et al simply does not teach or infer using near IR wavelengths to kill microbes.

Furthermore, while the Kumar et al device delivers near IR radiation to a patient, the energy output is too low for the generation of toxic oxygen species sufficient to cause bacterial photodamage, as Applicant claims. Kumar et al does not teach "*delivery of said first radiation*

and said second radiation from said laser oscillator sub-system through said optical channel to the site of said bacterial locale thereby selectively photodamaging bacteria without significant heat deposition to tissues in said bacterial locale; wherein said first radiation and said second radiation target a bacterial intracellular chromophore at said bacterial locale and generate radical oxygen species to photodamage bacteria in said bacterial locale” (emphasis added). For this reason, Kumar et al cannot anticipate Applicant’s invention.

L’Esperence and Neumann

The Office has rejected claims 21-31 under 35 U.S.C. § 103(a) as being unpatentable over L’Esperence Jr. in combination with Neumann et al., both of record.

Neumann et al. does not teach using lasers for *in vivo* phototherapy—to damage bacteria at a bacterial location. Neumann et al., teaches the use of various near infrared wavelengths on bacteria isolated by so-called optical traps. The reference explores a range of wavelengths at extremely high power densities, e.g., on the order of 1×10^7 W/cm², as typically used in such optical traps, which Applicant notes typically employ beam spot sizes on the order of a micron. The energy density of the laser systems described in Neumann et al. would not only be inappropriate for Applicant’s purposes, but intolerable; as would be the beam spot sizes used, which would produce an energy density sufficient to create great thermal damage to the surrounding tissues at the treatment site.

L’Esperance Jr. teaches the use of a multi-beam laser system for application to an area of prospective surgical invasion of living tissue. Regarding the light produced by such a multi-beam laser system, L’Esperance teaches that such light: “(a) is of low-to-moderate intensity a tissue impingement and (b) is also of spectral wavelength that is preferably in the visible or in the infrared.” L’Esperance, col. 2, lines, 7-10. This specification encompasses any wavelength beginning at 400 nm (visible blue) out to 100,000 nm (the threshold of microwaves). This broad and general description in L’Esperance Jr. of expansive portions of the electromagnetic spectrum fails to comprehend the significance, criticality, and unexpected results of the Applicant’s claimed near infrared wavelength ranges at relatively low power levels, for producing photodamage in bacteria at an infected site. Likewise, L’Esperence Jr. teaches the use of

exogenous agents, applied in advance of laser treatment, which are taken up by the microbes. Wavelength ranges are given, which exploit the photoabsorbtion profiles of these exogenous agents, where the agents themselves are chromophores that enhance the energy absorbtion and deposition within these microbial cells.

Applicant notes that MPEP § 716.02 and MPEP § 2144.05(III) set forth established law that holding that unexpected results arising from the criticality of a claimed subrange can provide for patentability of claims reciting the subrange. Such a claimed subrange can be patentable over any prior art which teaches broad ranges without comprehension of the uniqueness or unexpected results arising from the claimed subrange. As Applicant has stated in the subject application, the claimed near infrared wavelengths range of Applicant's invention are capable of treating bacteria in an infected site "with non-ionizing optical energy and minimal heat deposition." See, e.g., paragraph 13 of the subject application. Thus, L'Esperance Jr. teaches an enormously broad spectrum, very little of which could be used to produce the bacterial photodamage claimed by Applicant. L'Esperance fails to comprehend the uniqueness of the Applicant's claimed near infrared wavelengths and ranges, and does not teach or suggest the use of such specific and narrow wavelength ranges for producing photodamage *via* interaction with endogenous chromophores in bacteria at an infected site.

The combination of L'Esperance Jr. and Neumann et al. does not teach each and every limitation of the claims, and therefore the combination is an improper basis for a rejection of the claims under 35 U.S.C. § 103(a). Neither reference, alone or in combination teaches Applicant's methods of *selectively photodamaging bacteria without significant heat deposition to tissues in said bacterial locale*. Consequently, Applicant respectfully requests that the rejection of the claims under 35 U.S.C. § 103(a) in view of the L'Esperance Jr. and Neumann references be withdrawn and the claims allowed.

Provisional Claim Rejections – Double Patenting

The Office has provisionally rejected claims 21-22 of the application, under the judicially-created doctrine of obviousness-type double patenting, in view of Applicant's U.S.

Patent 7,255,560 and his applications: U.S.S.N. 10/961,796; U.S.S.N. 11/841,348; U.S.S.N. 11/848,517; and U.S.S.N. 11/880,769.

Applicant believes that the claims as amended obviate the double patenting rejections, and request withdrawal of the same. Alternatively, Applicant requests this rejection be held in abeyance until the patentability of the instant claims is established in view of the prior art rejections, and the patentability of the claims pending in the above cited applications is also resolved.

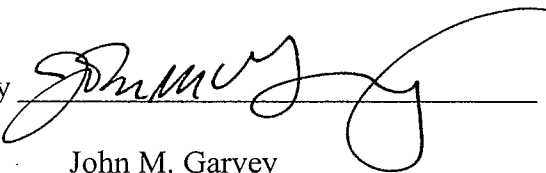
Conclusion

Applicant submits that the present application is in condition for allowance and such action is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application. The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741, reference docket number 093991-0019. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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